

OCT 15 2001

K013121  
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**1.2 510(k) Summary**

Sierra BioSearch, Inc.  
395 Mt. Tom Road  
Bishop, California 93514

**510(k) Summary of Safety and Effectiveness**

***Identification of the Device***

<b><i>Proprietary-Trade Name:</i></b>	MT Alert Infusion Monitor
<b><i>Classification Name:</i></b>	Monitor, Electric for Gravity Flow Infusion Systems
<b><i>Device Class:</i></b>	II
<b><i>Product Code:</i></b>	FLN
<b><i>Common/Generic Name:</i></b>	Gravity Infusion Monitor

***Equivalent Predicate Devices***

The MT Alert Infusion Monitor is substantially equivalent in design and function to the Smith & Nephew Dyonics LeveLert System.

***Indications for Use***

MT Alert Infusion Monitor is intended for use in any healthcare setting where gravity-flow infusions are utilized.

***Description of the Device***

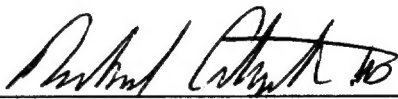
The MT Alert Infusion Monitor is a passive weighing device that alarms when the infusion bag is near-empty. The alarm point can be set by the user. In addition, MT Alert may also assist in monitoring fluid bolus administration. MT Alert will alarm when a prescribed bolus of fluid has been taken from the infusion bag. MT Alert provides various audio and visual alarms. MT Alert operates from common alkaline batteries and mounts on common poles and rods.

***Safety and Effectiveness in Comparison to Predicate Devices.***

The validation procedures performed on the system indicate that the new device is as safe and effective as the predicate devices.

**Substantial Equivalence Chart**

<b>Feature</b>	<b>MT Alert™</b>	<b>LeveLert</b>
Used for monitoring the fluid level of an infusion bag.	Yes	Yes
Automatic alarm when the fluid level has reached a pre-determined weight with audio and visual alarms.	Yes	Yes
Adjustable near-empty alarm point.	Yes- Easily programmed by hanging the desired weight.	Yes.
Accommodates most typical infusion bag sizes.	Yes (up to 3 liter size)	Yes (up to 3 liter size)
Bolus monitoring feature.	Yes (1 liter mode only)	No.
Passive device, no fluid control functions.	Yes	Yes
Infusion Container hangar.	Yes	Yes
Pole Mounting.	Yes	Yes
Power	2- AA batteries, typical 180 day life	Powered externally
Device Class.	Class II	Class II



Richard Citrenbaum, MD, President

19013121  
(Premarket Notification [510(k)] Number)



OCT 15 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Dr. Richard Citrenbaum  
President  
Sierra BioSearch, Incorporated  
395 Mount Tom Road  
Bishop, California 93514

Re: K013121

Trade/Device Name: MT Alert Infusion Monitor  
Regulation Number: 880.2420  
Regulation Name: Monitor, Electric for Gravity Flow Infusion Systems  
Regulatory Class: II  
Product Code: FLN  
Dated: September 14, 2001  
Received: September 18, 2001

Dear Dr. Citrenaum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

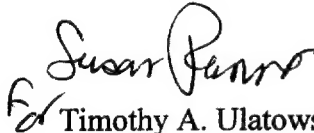
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Timothy A. Ulatowski".

Timothy A. Ulatowski

Director

Division of Dental, Infection Control  
and General Hospital Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

### 1.3 Statement of Indications for Use

Sierra BioSearch, Inc.  
395 Mt. Tom Road  
Bishop, California 93514

### Statement of Indications for Use

MT Alert Infusion Monitor is intended for use in any healthcare setting where gravity-flow infusions are utilized.

The device monitors the weight of the infusion bag and sounds an audible alarm to alert users of various gravity infusion end-points. These end-points include (1) near-empty condition and (2) fluid bolus completion..

Current practice typically involves visual monitoring of infusion bags by healthcare personnel for near-empty condition and for fluid bolus completion. Although the MT Alert Infusion Monitor in no way affects the safe use of a gravity IV, it can improve efficiency within a busy medical setting by notifying healthcare personnel of gravity infusion end-points. This alert system allows for timely replacement of intravenous or irrigation bags and prompts healthcare providers to reevaluate the infusion rate at the completion of a 250 or 500ml fluid bolus.

B. Bricker  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K013121